

Food and Drug Administration, HHS

§ 558.311

Laidlomycin in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(2) 5	Chlortetracycline 10 mg/lb body weight.	For improved feed efficiency and increased rate of weight gain; and for treatment of bacterial enteritis caused by <i>E. coli</i> and bacterial pneumonia caused by <i>Pasteurella multocida</i> organisms susceptible to chlortetracycline..	Feed continuously at a rate of 30 to 75 mg laidlomycin propionate potassium per head per day for not more than 5 days. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal..	046573
(3) 5	Chlortetracycline 350 mg/head/day.	For improved feed efficiency and increased rate of weight gain; and for control of bacterial pneumonia associated with shipping fever complex caused by <i>Pasteurella</i> spp. susceptible to chlortetracycline..	Feed continuously at a rate of 30 to 75 mg laidlomycin propionate potassium per head per day. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal..	046573
(4) 5 to 10	For improved feed efficiency.	Feed continuously in a Type C feed at a rate of 30 to 150 milligrams/head/day..	046573
(5) 5 to 10	Chlortetracycline 10 mg/pound body weight.	For improved feed efficiency; and for treatment of bacterial enteritis caused by <i>E. coli</i> and bacterial pneumonia caused by <i>P. multocida</i> organisms susceptible to chlortetracycline..	Feed continuously at a rate of 30 to 150 mg laidlomycin propionate potassium per head per day for not more than 5 days. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal..	046573
(6) 5 to 10	Chlortetracycline 350 mg/head/day.	For improved feed efficiency; and for control of bacterial pneumonia associated with shipping fever complex caused by <i>Pasteurella</i> spp. susceptible to chlortetracycline..	Feed continuously at a rate of 30 to 150 mg laidlomycin propionate potassium per head per day. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal..	046573

[59 FR 18297, Apr. 18, 1994, as amended at 60 FR 53509, Oct. 16, 1995; 62 FR 9929, Mar. 5, 1997; 63 FR 27845, May 21, 1998; 66 FR 46706, Sept. 7, 2001; 68 FR 13839, Mar. 21, 2003; 68 FR 42590, July 18, 2003; 69 FR 30198, May 27, 2004]

§ 558.311 Lasalocid.

(a) *Specifications.* A minimum of 90 percent of lasalocid activity is derived from lasalocid A.

(b) *Approvals.* Type A medicated articles approved for sponsors identified in § 510.600(c) of this chapter for use as in paragraph (e) of this section as follows:

(1) 3.0, 3.3, 3.8, 4.0, 4.3, 4.4, 5.0, 5.1, 5.5, 5.7, 6.0, 6.3, 6.7, 7.2, 7.5, 8.0, 8.3, 10.0, 12.5, 15, 20, and 50 percent activity to No. 046573 for use as in paragraphs (e)(1)(i), (ii), (iii), (iv), and (x) of this section.

(2) 15 percent activity to No. 066104 as provided by No. 046573 for use as in paragraph (e)(1)(v) of this section.

(3) 15, 20, 33.1, and 50 percent activity to No. 046573 for use in cattle feeds as in paragraphs (e)(1)(vi), (vii), (ix), (xi), (xii), and (xv) of this section, and for

use in sheep as in paragraph (e)(1)(viii) of this section.

(4) 15 percent activity to No. 046573 for use in Type C rabbit feeds as in paragraph (e)(1)(xvi) of this section and for use in ruminant free-choice Type C feeds as in paragraphs (e)(2), (e)(3), and (e)(4) of this section.

(5) 15 percent activity to 021930 (Type A article provided by 046573) for use in free-choice vitamin-mineral Type C cattle feeds as in paragraph (e)(1)(xi).

(6) 20 percent activity as a liquid Type A article to No. 046573 for use in cattle feeds as in paragraphs (e)(1)(vi), (e)(1)(vii), (e)(1)(ix), (e)(1)(xi), (e)(1)(xii), and (e)(3) of this section, and for use in sheep feeds as in paragraph (e)(1)(viii) of this section.

(7) 20 percent activity to No. 046573 for use as follows:

- (i) Chukar partridges as in paragraph (e)(1)(xiii).
- (ii) Turkeys as in paragraph (e)(1)(xiv).
- (iii) Rabbits as in paragraph (e)(1)(xvi).

(8) 15 percent activity to No. 017800 for use as in paragraph (e)(1)(xviii) of this section.

(9) 15 percent activity to No. 068287 for use in free-choice protein blocks for cattle as in paragraphs (e)(1)(xix) of this section.

(c) *Related tolerance.* See § 556.347 of this chapter.

(d) *Special considerations.* (1) Type C cattle and sheep feeds may be manufactured from lasalocid liquid Type B feeds which have a pH of 4.0 to 8.0 and bear appropriate mixing directions as follows:

(i) For liquid feeds stored in recirculating tank systems: Recirculate immediately prior to use for no less than 10 minutes, moving not less than 1 percent of the tank contents per minute from the bottom of the tank to the top. Recirculate daily as described even when not used.

(ii) For liquid feeds stored in mechanical, air, or other agitation-type tank systems: Agitate immediately prior to use for not less than 10 minutes, creating a turbulence at the bottom of the tank that is visible at the top. Agitate daily as described even when not used.

(2) A physically stable lasalocid liquid feed will not be subject to the requirements for mixing directions prescribed in paragraph (d)(1) of this section provided it has a pH of 4.0 to 8.0 and contains a suspending agent(s) sufficient to maintain a viscosity of not

less than 300 centipoises per second for 3 months.

(3) If a manufacturer is unable to meet the requirements of paragraph (d)(1) or (d)(2) of this section, the manufacturer may secure approval of a positionally stable liquid feed by:

(i) Either filing a new animal drug application for the product or establishing a master file containing data to support the stability of its product;

(ii) Authorizing the agency to reference and rely upon the data in the master file to support approval of a supplemental new animal drug application to establish physical stability; and

(iii) Requesting the sponsor of an approved new animal drug application to file a supplement to provide for use of its lasalocid Type A article in the manufacture of the liquid feed specified in the appropriate master file. If the data demonstrate the stability of the liquid feed described in the master file, the supplemental new animal drug application will be approved. The approval will provide a basis for the individual liquid feed manufacturer to manufacture under a medicated feed license the liquid mediated feed described in the master file. A manufacturer who seeks to market a physically unstable lasalocid liquid feed with mixing directions different from the standard directions established in paragraph (d)(1) of this section may also follow this procedure.

(4) If adequate information is submitted to show that a particular liquid feed containing lasalocid is stable outside the pH of 4.0 to 8.0, the pH restriction described in paragraphs (d)(1) and (d)(2) of this section may be waived.

(e)(1) *Conditions of use.* It is used as follows:

Lasalocid sodium activity in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(i) 68 (0.0075 pct) to 113 (0.0125 pct).	For the prevention of coccidiosis caused by <i>Eimeria tenella</i> , <i>E. necatrix</i> , <i>E. acervulina</i> , <i>E. brunetti</i> , <i>E. mivati</i> , and <i>E. maxima</i> .	For broiler or fryer chickens only; feed continuously as the sole ration.	046573
(ii) 68 (0.0075 pct) to 113 (0.0125 pct).	Roxarsone 45.4 (0.005 pct).	Broiler or fryer chickens; for the prevention of coccidiosis caused by <i>Eimeria tenella</i> , <i>E. necatrix</i> , <i>E. acervulina</i> , <i>E. brunetti</i> , <i>E. mivati</i> , and <i>E. maxima</i> and as an aid in the reduction of lesions due to <i>E. tenella</i> .	For broiler or fryer chickens only; feed continuously as the sole ration; as sole source of organic arsenic; withdraw 5 d before slaughter; roxarsone provided by Nos. 046573 and 011526 in § 510.600(c) of this chapter.	046573

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Lasalocid sodium activity in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
	Roxarsone 45.4 plus bambermycins 1 (0.00011 pct).	For prevention of coccidiosis caused by <i>Eimeria tenella</i> , <i>E. necatrix</i> , <i>E. acervulina</i> , <i>E. brunetti</i> , <i>E. mivati</i> , and <i>E. maxima</i> ; as an aid in the reduction of lesions due to <i>E. tenella</i> ; and for increased rate of weight gain.	For broiler chickens only; feed continuously as sole ration; withdraw 5 days before slaughter; roxarsone provided by Nos. 046573 and 011526 in § 510.600(c) of this chapter, bambermycins provided by No. 012799.	046573
	Roxarsone 45.4 plus lincomycin 2.0.	For prevention of coccidiosis caused by <i>Eimeria tenella</i> , <i>E. necatrix</i> , <i>E. acervulina</i> , <i>E. brunetti</i> , <i>E. mivati</i> , and <i>E. maxima</i> ; as an aid in the reduction of lesions due to <i>E. tenella</i> ; and for increased rate of weight gain and improved feed efficiency.	For broiler chickens only; feed continuously as sole ration; withdraw 5 days before slaughter; roxarsone provided by Nos. 046573 and 011526 in § 510.600(c) of this chapter, lincomycin provided by No. 000009.	046573
	Roxarsone 45.4 plus bacitracin 10 to 25.	For prevention of coccidiosis caused by <i>Eimeria tenella</i> , <i>E. necatrix</i> , <i>E. acervulina</i> , <i>E. brunetti</i> , <i>E. mivati</i> , and <i>E. maxima</i> ; as an aid in the reduction of lesions due to <i>E. tenella</i> ; and for increased rate of weight gain.	For broiler or fryer chickens only; feed continuously as the sole ration; withdraw 5 days before slaughter; roxarsone provided by Nos. 046573 and 011526 in § 510.600(c) of this chapter, bacitracin methylene disalicylate provided by No. 046573 in § 510.600(c) of this chapter.	046573
	Roxarsone 45.4 plus bacitracin 10 or 30.	For prevention of coccidiosis caused by <i>E. tenella</i> , <i>E. necatrix</i> , <i>E. acervulina</i> , <i>E. brunetti</i> , <i>E. mivati</i> and <i>E. maxima</i> ; as an aid in the reduction of lesions due to <i>E. tenella</i> ; and for increased rate of weight gain (10 grams per ton) or improved feed efficiency (30 grams per ton).	For broiler chickens only; feed continuously as sole ration; withdraw 5 days before slaughter; roxarsone provided by Nos. 046573 and 011526 in § 510.600(c) of this chapter, bacitracin zinc provided by No. 000004.	046573
	Roxarsone 45.5 plus bacitracin methylene disalicylate 50.	Prevention of coccidiosis caused by <i>Eimeria necatrix</i> , <i>E. tenella</i> , <i>E. acervulina</i> , <i>E. brunetti</i> , <i>E. mivati</i> , and <i>E. maxima</i> ; reduction of lesions due to <i>E. tenella</i> ; prevention of necrotic enteritis caused or complicated by <i>Clostridium</i> spp. or other susceptible organisms.	Feed continuously as sole ration; as sole source of organic arsenic; withdraw 5 days before slaughter.	046573
(iii) 68 (0.0075 pct).	Lincomycin 2 (0.00022 pct).	Broiler or fryer chickens; for the prevention of coccidiosis caused by <i>Eimeria mivati</i> , <i>E. brunetti</i> , <i>E. tenella</i> , <i>E. acervulina</i> , <i>E. maxima</i> , and <i>E. necatrix</i> ; for increased rate of weight gain and improved feed efficiency.	For broiler and fryer chickens only; feed continuously as sole ration; withdraw 5 d before slaughter; Type C feed must be used within 4 weeks of manufacture; as lincomycin hydrochloride monohydrate.	046573
(iv) 68 (0.0075 percent).	Bacitracin 10 to 50 ..	For prevention of coccidiosis caused by <i>Eimeria tenella</i> , <i>E. necatrix</i> , <i>E. acervulina</i> , <i>E. brunetti</i> , <i>E. mivati</i> , and <i>E. maxima</i> , and for increased rate of weight gain and improved feed efficiency.	For broiler or fryer chickens only; feed continuously as the sole ration; bacitracin methylene disalicylate provided by No. 046573 in § 510.600(c) of this chapter.	046573
(v) 68 (0.0075 pct) to 113 (0.0125 pct).	Virginiamycin 20	For prevention of coccidiosis caused by <i>Eimeria tenella</i> , <i>E. necatrix</i> , <i>E. acervulina</i> , <i>E. brunetti</i> , <i>E. mivati</i> , and <i>E. maxima</i> , and for increased rate of weight gain and improved feed efficiency.	For broiler and fryer chickens only; feed continuously as sole ration; do not feed to laying chickens; lasalocid sodium provided by No. 046573 in § 510.600(c) of this chapter.	046573
(vi) 10 (0.0011 pct) to 30 (0.0033 pct).	Cattle; for improved feed efficiency	In Type C feeds; for cattle fed in confinement for slaughter only; feed continuously in complete feed to provide not less than 100 mg nor more than 360 mg of lasalocid sodium activity per head per day.	046573

Lasalocid sodium activity in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(vii) 25 (0.0027 pct) to 30 (0.0033 pct).	Oxytetracycline 7.5 ..	Cattle: for improved feed efficiency and reduction of incidence and severity of liver abscesses.	In Type C feeds, for beef cattle fed in confinement for slaughter; feed continuously at 100 to 360 mg/head/day lasalocid and 75 mg/head/day oxytetracycline. As monoalkyl (C ₈ –C ₁₈) trimethyl ammonium oxytetracycline.	046573
	Cattle; for improved feed efficiency and increased rate of weight gain.	In Type C feeds; for cattle fed in confinement for slaughter only; feed continuously in complete feed to provide not less than 250 mg nor more than 360 mg of lasalocid sodium activity per head per day.	046573
	Oxytetracycline 7.5 ..	Cattle: for improved feed efficiency, increased rate of weight gain, and reduction of incidence and severity of liver abscesses.	In Type C feeds, for beef cattle fed in confinement for slaughter; feed continuously at 250 to 360 mg/head/day lasalocid and 75 mg/head/day oxytetracycline. As monoalkyl (C ₈ –C ₁₈) trimethyl ammonium oxytetracycline.	046573
(viii) 20 (0.0022 pct) to 30 (0.0033 pct).	Sheep; for the prevention of coccidiosis caused by <i>Eimeria ovina</i> , <i>E. crandallis</i> , <i>E. ovinoidalis</i> (<i>E. ninakohlyakimovae</i>), <i>E. parva</i> , and <i>E. intricata</i> .	In Type C feeds; for sheep maintained in confinement; feed continuously in complete feed to provide not less than 15 mg nor more than 70 mg of lasalocid sodium activity per head per day depending on body weight.	046573
(ix)	Pasture cattle (slaughter, stocker, feeder cattle, and dairy and beef replacement heifers): for increased rate of weight gain. Intakes of lasalocid in excess of 200 mg/head/day have not been shown to be more effective than 200 mg/head/day..	Feed continuously at a rate of not less than 60 mg or more than 300 mg of lasalocid per head per day when on pasture; the drug must be contained in at least 1 pound of feed..	046573
(x) 68 (0.0075 pct) to 113 (0.0125 pct).	Bacitracin 4 to 50	Broiler chickens; for prevention of coccidiosis caused by <i>Eimeria tenella</i> , <i>E. necatrix</i> , <i>E. acervulina</i> , <i>E. brunetti</i> , <i>E. mivati</i> , and <i>E. maxima</i> ; and for improved feed efficiency.	For broiler chickens only; feed continuously as the sole ration; bacitracin methylene disalicylate provided by No. 046573 in § 510.600(c) of this chapter.	046573
(xi) 68 (0.0075 pct) to 113 (0.0125 pct)..	Bacitracin zinc 4 to 50..	Broiler chickens. For prevention of coccidiosis caused by <i>Eimeria tenella</i> , <i>E. necatrix</i> , <i>E. acervulina</i> , <i>E. brunetti</i> , <i>E. mivati</i> , and <i>E. maxima</i> , and for increased rate of weight gain and improved feed efficiency..	Feed continuously as sole ration. Bacitracin zinc and lasalocid sodium as provided by No. 046573 in § 510.600(c) of this chapter..	046573
(xii)	Pasture cattle (slaughter, stocker, feeder cattle, and dairy and beef replacement heifers): For increased rate of weight gain. Intakes of lasalocid in excess of 200 mg/head/day have not been shown to be more effective than 200 mg/head/day..	Feed continuously on a free-choice basis at a rate of not less than 60 mg or more than 300 mg of lasalocid per head per day..	046573
(xiii)	Cattle; for control of coccidiosis caused by <i>Eimeria bovis</i> and <i>Eimeria zuernii</i> .	For cattle; hand feed at a rate of 1 mg of lasalocid per 2.2 pounds body weight per day to cattle weighing up to 800 pounds with a maximum of 360 mg of lasalocid per head per day.	046573
(xiv) 113 (0.0125 pct)..	Chukar partridges; for prevention of coccidiosis caused by <i>Eimeria legionensis</i> .	Feed continuously as sole ration up to 8 weeks of age.	046573

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Lasalocid sodium activity in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(xv) 68 (0.0075 pct) to 113 (0.0125 pct).	Growing turkeys; for prevention of coccidiosis caused by <i>E. meleagrimitis</i> , <i>E. gallopavonis</i> , and <i>E. adenoeides</i> ..	Feed continuously as sole ration.	046573
.....	Bacitracin 4 to 50	Growing turkeys; for prevention of coccidiosis caused by <i>E. meleagrimitis</i> , <i>E. gallopavonis</i> , and <i>E. adenoeides</i> ; for increased rate of weight gain and improved feed efficiency..	Feed continuously as sole ration.	046573
.....	Bacitracin methylene disalicylate 4 to 50.	Growing turkeys; for prevention of coccidiosis caused by <i>E. meleagrimitis</i> , <i>E. gallopavonis</i> , and <i>E. adenoeides</i> ; for increased rate of weight gain and improved feed efficiency..	Feed continuously as sole ration. Bacitracin methylene disalicylate as provided by No. 046573 in § 510.600(c) of this chapter..	046573
.....	Virginiamycin 10 to 20.	Growing turkeys; for prevention of coccidiosis caused by <i>E. meleagrimitis</i> , <i>E. gallopavonis</i> , and <i>E. adenoeides</i> , and for increased rate of weight gain and improved feed efficiency..	Feed continuously as sole ration. As lasalocid sodium provided by 063238 and virginiamycin provided by 066104..	046573
(xvi)	Replacement calves; for control of coccidiosis caused by <i>E. bovis</i> and <i>E. zuernii</i> ..	In milk replacer powder; hand feed at a rate of 1 mg of lasalocid per 2.2 lb body weight per day; include on labeling warning: "A withdrawal period has not been established for lasalocid in pre-ruminating calves. Do not use in calves to be processed for veal".	046573
(xvii) 113 (0.0125 pct)..	Rabbits; for prevention of coccidiosis caused by <i>Eimeria stiedae</i> .	Feed continuously as sole ration up to 6 1/2 weeks of age.	046573
(xviii) 1440	Pasture cattle (slaughter, stocker, feeder cattle, and dairy and beef replacement heifers): For increased rate of weight gain..	Feed continuously on a free-choice basis at a rate of not less than 60 mg nor more than 200 mg of lasalocid per head per day..	021930 017800
(xix) 300	Pasture cattle (slaughter, stocker, feeder cattle, and dairy and beef replacement heifers): for increased rate of weight gain..	Feed continuously on a free-choice basis at a rate of not less than 60 mg nor more than 200 mg of lasalocid per head per day..	068287

(2) It is used as a free-choice mineral Type C feed as follows:

(i) *Specifications.*

Ingredient	Percent	International feed No.
Defluorinated Phosphate (20.5 percent Calcium, 18.5 percent Phosphorus)	35.9	6-01-080
Sodium Chloride (Salt)	20.0	6-04-152
Calcium Carbonate (38 percent Calcium)	18.0	6-01-069
Cottonseed Meal	10.0	5-01-621
Potassium Chloride	3.0	6-03-755
Selenium Premix (0.02 percent Selenium) ¹	3.0	
Dried Cane Molasses	2.5	4-04-695
Magnesium Sulfate	1.7	6-02-758
Vitamin Premix ¹	1.4	
Magnesium Oxide	1.2	6-02-756
Potassium Sulfate	1.2	6-06-098
Trace Mineral Premix ¹	1.04	
Bovatec Premix (68 grams per pound)	1.06	

¹ Content of this vitamin and trace mineral premixes may be varied; however, they should be comparable to those used by the firm for other free-choice feeds. Formulation modifications require FDA approval prior to marketing. Selenium must comply with § 573.920 of this chapter. Ethylenediamine dihydroiodide (EDDI) should comply with FDA Compliance Policy Guide Sec. 651.100 (CPG 7125.18).

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(ii) *Amount.* 1,440 grams per ton (0.16 percent).

(iii) *Indications for use.* Pasture cattle (slaughter, stocker, feeder cattle, and dairy and beef replacement heifers): for increased rate of weight gain. Intakes of lasalocid in excess of 200 mg/head/day have not been shown to be more effective than 200 mg/head/day.

(iv) *Limitations.* For pasture cattle (slaughter, stocker, feeder cattle, and

dairy and beef replacement heifers); feed continuously on a free-choice basis at a rate of 60 to 300 milligrams lasalocid per head per day.

(v) *Sponsor.* See No. 046573 in § 510.600(c) of this chapter.

(3) It is used as a ruminant free-choice liquid Type C feed as follows:

(i) *Specifications.*

Ingredient	Percent	International feed No.
Cane Molasses	55.167	4–13–241
Condensed Molasses Fermentation Solubles	24.0	N/A
50% Urea Solution (23% N)	12.0	N/A
Ammonium Polyphosphate Solution	1.0	6–08–42
Phosphoric Acid (54%)	3.0	6–03–707
Xanthan Gum	0.05	8–15–818
Water	4.0	N/A
Trace Mineral Mix ¹	0.5	N/A
Vitamin Premix ¹	0.2	N/A
Bovatec Liquid 20 (90.8 gm/lb) ²	0.083	N/A

¹Content of vitamin and trace mineral premixes may be varied; however, they should be comparable to those used for other free-choice liquid feeds. Formulation modifications require FDA approval prior to marketing. Selenium must comply with § 573.920 of this chapter. EDDI should comply with FDA Compliance Policy Guide Sec. 651.100 (CPG 7125.18).

² To provide 150 gm lasalocid per ton, use 1.652 lb (0.083%) of Bovatec Liquid 20 (90.8 gm/lb). If dry Bovatec-68 (68 gm/lb) is used, use 2.206 lbs per ton (0.111%), replacing molasses.

(ii) *Amount.* 150 grams per ton (.017 percent).

(iii) *Indications for use.* Pasture cattle (slaughter, stocker, feeder cattle, and dairy and beef replacement heifers): for increased rate of weight gain. Intakes of lasalocid in excess of 200 mg/head/day have not been shown to be more effective than 200 mg/head/day.

(iv) *Limitations.* For pasture cattle (slaughter, stocker, feeder cattle, and

dairy and beef replacement heifers). Feed continuously on a free-choice basis at a rate of 60 to 300 milligrams lasalocid per head per day.

(v) *Sponsor.* See No. 046573 in § 510.600(c) of this chapter.

(4) It is used as a free-choice, loose mineral Type C feed as follows:

(i) *Specifications.*

Ingredient	Percent	International feed No.
Monocalcium Phosphate (21% P)	57.70	6–01–082
Salt	17.55	6–04–152
Distillers Dried Grains w/Solubles	5.40	5–28–236
Dried Cane Molasses (46% Sugars)	5.20	4–04–695
Potassium Chloride	4.90	6–03–755
Trace Mineral/Vitamin Premix ¹	3.35	
Calcium Carbonate (38% Ca)	2.95	6–01–069
Mineral Oil	1.05	8–03–123
Magnesium Oxide (58% Mg)	1.00	6–02–756
Iron Oxide (52% Fe)	0.10	6–02–431
Lasalocid Type A Medicated Article (68 g per pound)	0.80	

¹ Content of vitamin and trace mineral premixes may be varied. However, they should be comparable to those used for other free-choice loose mineral feeds. Formulation modifications require FDA approval prior to marketing. Selenium must comply with § 573.920 of this chapter. EDDI should comply with FDA Compliance Policy Guides Sec. 651.100 (CPG 7125.18).

(ii) *Amount.* 1,088 grams per ton.

(iii) *Indications for use.* Pasture cattle (slaughter, stocker, feeder cattle, and dairy and beef replacement heifers): For increased rate of weight gain. Intakes of lasalocid in excess of 200 mg/

head/day have not been shown to be more effective than 200 mg/head/day.

(iv) *Limitations.* Feed continuously on a free-choice basis at a rate of 60 to 300 mg lasalocid per head per day.

(v) *Sponsor*. See No. 046573 in § 510.600(c) of this chapter.

(5) *Additional combinations*. Lasalocid may be used in accordance with the provisions of this section in combination as follows:

(i) Melengestrol acetate alone or in combination with tylosin in accordance with § 558.342.

(ii) Bambermycins as in § 558.95 of this chapter.

[41 FR 44382, Oct. 8, 1976]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 558.311, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and on GPO Access.

§ 558.315 Levamisole hydrochloride (equivalent).

(a) *Approvals*. Type A medicated articles: 227 grams per pound to No. 053501 in § 510.600(c) of this chapter.

(b) *Related tolerances*. See § 556.350 of this chapter.

(c) *Conditions of use*. It is used in Type C medicated feed as follows:

(1) *Cattle*—(i) *Amount per pound*. 0.36–3.6 grams (0.08–0.8 percent).

(ii) *Indications for use*. Treatment of the following gastrointestinal worms and lung worm infections; stomach worms (*Haemonchus*, *Trichostrongylus*, *Ostertagia*), intestinal worms (*Trichostrongylus Cooperia*, *Nematodirus*, *Bunostomum*, *Oesophagostomum*), and lungworms (*Dictyocaulus*).

(iii) *Limitations*. Administer medicated feed mixed thoroughly in one half the usual amount of morning feed; the medicated feed mix should be consumed within 6 hours; when medicated feed is consumed resume normal feeding; medicated feed is to be fed at the rate of 0.36 gram of levamisole hydrochloride (equivalent) per 100 lb. of body weight; conditions of constant helminth exposure may require retreatment within 2 to 4 weeks after the first treatment; do not slaughter for food within 48 hours of treatment; consult veterinarian before using in severely debilitated animals; do not administer to dairy animals of breeding age; for use in pelleted or meal feeds only; the label shall bear the caution, "Muzzle foam may be observed. However, this reaction will disappear within a few hours. If this condition per-

sists, a veterinarian should be consulted. Follow recommended dosage carefully."

(2) *Swine*—(i) *Amount per pound*. 0.36 grams (0.08 percent).

(ii) *Indications for use*. Treatment of the following nematode infections: large roundworms (*Ascaris suum*), nodular worms (*Oesophagostomum* spp.), lungworms (*Metastrongylus* spp.), intestinal threadworms (*Strongyloides ransomi*), swine kidney worms (*Stephanurus dentatus*).

(iii) *Limitations*. It is recommended that regular feed be withheld overnight and worming feed administered the following morning; dilute supplement with nonmedicated feed as directed; feed the equivalent of 1 lb. of 0.08 percent worming feed per 100 lbs. of body weight of pigs to be treated; may be fed as sole feed or thoroughly mixed with 1 to 2 parts of regular feed prior to feeding; when medicated feed is consumed, resume normal feeding. Pigs maintained under conditions of constant worm exposure may require retreatment within 4 to 5 weeks after the first treatment due to reinfection; do not slaughter for food within 72 hours of treatment; the label shall bear the caution, "Excessive salivation or muzzle foam may be observed. This reaction is occasionally seen and will disappear in a short time after medication. If pigs are infected with mature lungworms, coughing and vomiting may be observed soon after medicated feed is consumed. This reaction is due to the expulsion of worms from the lungs and will be over in several hours."

[40 FR 13959, Mar. 27, 1975, as amended at 43 FR 11176, Mar. 17, 1978; 43 FR 39351, Sept. 5, 1978; 43 FR 16013, Mar. 16, 1979; 51 FR 7398, Mar. 3, 1986; 67 FR 63055, Oct. 10, 2002]

§ 558.325 Lincomycin.

(a) *Approvals*. Type A articles and Type B feeds approved for sponsors in § 510.600(c) of this chapter for specific uses as in paragraph (d) of this section as follows:

(1) No. 000009 for 20 and 50 grams per pound.

(2)–(4) [Reserved]

(5) No. 043733 for 8 and 20 grams per pound.

(6)–(12) [Reserved]